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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,906	05/26/2006	Kohji Fukatsu	20039.0005USWO	7379
52835 7590 09/07/2010 HAMRE, SCHUMANN, MUELLER & LARSON, P.C. P.O. BOX 2902 MINNEAPOLIS, MN 55402-0902				
EXAMINER KATAKAM, SUDHAKAR				
ART UNIT 1621		PAPER NUMBER		
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/580,906

**Applicant(s)**

FUKATSU ET AL.

**Examiner**

SUDHAKAR KATAKAM

**Art Unit**

1621

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 August 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 6, 10, 14, 15 and 18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6, 10, 14, 15 and 18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 May 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Paper No(s)/Mail Date \_\_\_\_\_
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Status of the application***

1. Receipt of Applicant's remarks and arguments filed on 18 Aug 2010 is acknowledged.
2. In view of applicants' cancellation of claims and amendments to the claims, the previous rejections have been withdrawn.
3. However, upon further consideration, in view of applicants' amendments to the claims, a new ground(s) of rejection is made in view of newly found prior art and provide an explanation of the rejection.

### ***Claim Objections***

4. Claim 6 is objected to because of the following informalities: the print/image of the structure of formula (II) in the claim is not clear. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 6, 10 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim subject matter which applicant regards as the invention.

In the claim 6, the definition for the group is 'X' is missing. Also the meaning of the dotted line between R<sup>c</sup> and R<sup>d</sup> is missing. Therefore, it is impossible to determine the metes and bounds of the claimed subject matter. Claim 6 and its dependent claims are therefore rendered indefinite.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

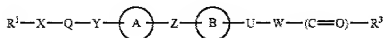
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 6, 10, 14, 15 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Momose et al** (US 7,238,716 B2).

**Momose et al** teach the following compound:



, which reads instant

claims, when  $R^3$  is -OH group, -U-W- is -CH<sub>2</sub>-, B is a benzene ring optionally has 1 to 3 substituents, Z is -CH<sub>2</sub>O-, A is aromatic ring optionally having 1 to 3 substituents, -X-Q-Y- is -CH<sub>2</sub>O- and  $R^1$  is hetero ring [See column 4].

**Momose et al** also teach halogen, preferably F, Cl or Br, on the ring B [col.22, lines 1-5 and 54-67].

**Momose et al** deficient in the sense that it fails to exemplify applicants' specific compounds. However, obvious to arrive at applicants compounds for the following reasons:

The claims would have been obvious because, a person of ordinary skill has a good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product, not of innovation, but of ordinary skill and common sense. In this case, **Momose et al** clearly suggested applicants' core structure with a small group of possible species. Therefore, a skilled person in the art would be motivated to explore other possible species encompassed in the generic formula of **Momose et al**.

The claim would have been obvious because the design incentives or market forces provided a reason to make an adaptation, and the invention resulted from application of the prior knowledge in a predictable manner. In this case, the commercial importance of applicants' core structure, and its commercial importance in the pharmaceutical industry, as evidenced by teachings of **Momose et al**.

All the claimed elements were known in the prior art and one skilled person in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to have yielded predictable results to one of ordinary skill in the art at the time of the invention. In this case, **Momose et al** teach all elements of applicants' compound, and a skilled person in the art would go through a routine experimentation and to arrive at applicants' compound with a reasonable expectation of success.

Therefore, it would have been obvious to a person of ordinary skill in the art, at the time of present invention was made, to have modified the reference's teachings, to achieve applicants' compound(s), with a reasonable expectation of success. Applicants are invited to provide a showing which is commensurate in scope with the claimed invention that clearly demonstrate that the claimed compounds result in some unexpected property over the disclosure of the prior art.

### ***Double Patenting***

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Omum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 6, 10, 14, 15 and 18 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the claims 13, 16-23, 34, 38 and 39 of copending US application No. 10/534,081.

Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons:

They generically overlap. Both instant application and copending application claims are drawn to a compound, having the common structural core.

The differences are as follows: the claims of copending application are broad in the sense, whereas the claims of instant are specific in nature. For example, in the copending application the ring R is a phenylene group optionally having substituents, whereas in the instant claims the phenylene group has substituents of F or Cl etc.

It would have been a prima facie obvious at the time the invention was made to one of ordinary skill in the art to start with the teachings of the copending application and to arrive at instant applicant's compound with a reasonable expectation of success. The difference, however, does not constitute a patentable distinct, because the claims in the present invention simply fall within the scope of the copending application, since the similar core structure and substituents. Hence the instant claims overlap with the claims of the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not been patented yet.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Conclusion***

13. No claim is allowed.
14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sudhakar Katakam whose telephone number is 571-272-9929. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel Sullivan can be reached on 571-272-0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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